(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 749 758 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
27.12.1996 Bulletin 1996/52

(51) Int Cl.[6]: A61M 5/20, A61M 5/46

(21) Application number: 96850116.3

(22) Date of filing: 20.06.1996

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: 22.06.1995 SE 9502285

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(54) Improvements related to injections

(57) Disclosed are methods and means for facilitating injection which enable a correct penetration depth of the needle. These improvements are obtainable by using a needle covering device comprising an axially displaceable first tubular sleeve (30) arranged around the front part of said injection apparatus which at its foremost part surrounds the needle (11) over its entire length, and while overcoming a spring force, is axially displaceable rearwards to expose a predetermined length of the needle, said device further comprises a stationary outer tubular sleeve (40) releasably attached to the injection apparatus and fitted around the front part of said injection apparatus and an inner adjustable tubular stopping sleeve (20) which is axially displaceable between at least two predetermined positions while performing a sliding, helical motion around said front part of said injection apparatus when setting the distance between the foremost part of said stopping sleeve and a stopping flange (31) arranged on the inside of the axially displaceable first sleeve.

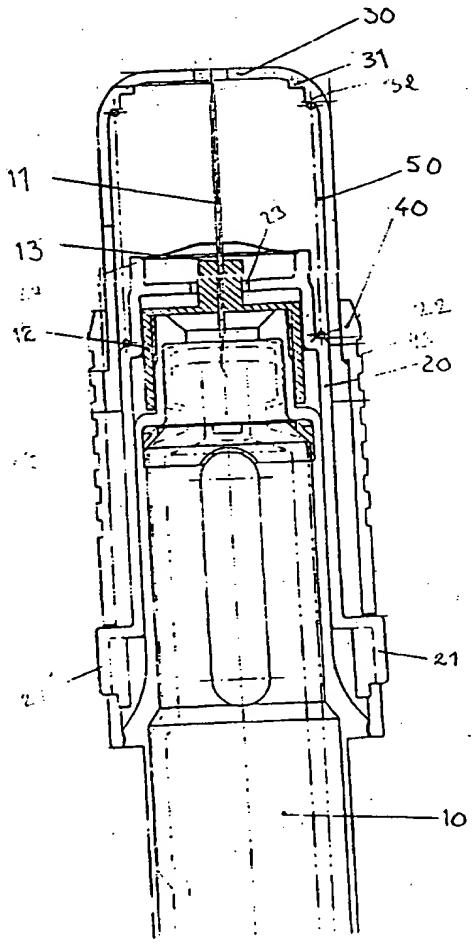

Fig. 1

EP 0 749 758 A1

Description

The present invention is related to facilitating injection, especially subcutaneous injection by providing a means and methods which enable a correct penetration depth of the needle and thereby a correct therapeutical effect from injected drug even if the injection site is altered by the patient.

It is highly desirable for a manufacturer and supplier of pharmaceuticals to meet the demands from patients who are confined to a long time regimen of adminstration by self-injections. Such patents require safe and convenient equipment which to the highest possible extent liberate them from the burden of repeated drug taking by injections. It must also be considered that many such patients are elderly or of infant age and might have a reduced physical strength and a strong aversion of needles. Many attempts have therefore been made to provide injection devices which hide or cover the needle for the user and only exposes it at the moment of adminstration. These devices have also the advantage that they cover the needle from inadvertent contamination before adminstration and also provides safety from accidental needle sticks from the used needle. Another requirement set on self -injections is that they must be repeatable in order to provide the patient with a correct dose of the pharmaceutical. Since the bioabsorption may vary considerable for a given drug dependent on the whether it is administered subcutaneously or intramusculary, it is of high importance to have a fixed penetration depth of the needle for repeated injections. An inaccurate injection depth may even in certain applications lead to varied effect of the drug which for example for a diabetic dependent on insulin might have fatal consequences.

A means which can be used on injection device for limiting the penetration of the needle which also entirely covers the needle for the user is disclosed in the International patent application PCT/SE92/00596. With this needle cover it is, however, not, possible to adjust the penetration depth of the needle, which is a drawback for especially when it is desired to inject the drug into the subcutaneous fat layer. A penetration depth adjustment is especially advantageous when injecting drugs subcutaneously, because the subcutaneous fat layer does not only vary considerably between individual patients, it also varies a between different parts of an individual body, for example between the thigh, the abdominal area, the arms and the legs. For many drugs, especially polypeptides or proteins like insulin, factor VIII and human growth hormone, also the bioabsorption may vary considerably between intramuscular and subcutaneous adminstration and also many times locally between different subcutaneous injection sites. In addition, many such drugs might demonstrate an improved activity when administered subcutaneously such as the factor VIII-preparations disclosed in the International patent applications WO 95/01804 and PCT/SE95/00348.

It would therefore be a significant improvement in convenience and safety for many patients to obtain an injection device which can give them a higher freedom to select and alter the injection site, while retaining a correct injection depth for each adminstration so a repeated drug effect is maintained.

It would also be an improvement to be able to benefit from the advantages of subcutaneous adminstration and be able to freely select subcutaneous injection sites after individual desire.

The object of the present invention is to provide a device which maintains all the advantages of a needle covering device while also making it possible to readily adjust the needle penetration depth between different pre-set values. This object is attained by the needle covering device as defined in claim 1.

It is also the object of the present invention to is provide a method of adjusting the penetration depth of the needle of an injection apparatus. This object is attained by the method in accordance with claim 8 wherein a characteristic needle covering device is employed.

Another object of the present invention to provide an improved method of administering a drug by subcutaneous injection so that a correct penetration depth of the injection needle in the subcutaneous fat layer of patient always is obtained. This object is attained by the method of claim 11.

A further object of the invention is to provide a kit for subcutaneous injection comprising an injection apparatus and a tubular needle covering device attachable thereto, by means of which a correct subcutaneous injection can be obtained irrespective of the injection site. This object is attained by the kit of claim 14.

A preferred embodiment of the present invention is now described in detail with reference to the appended drawings.

Fig. 1 shows a needle covering device providing a pre-set penetration depth, according to the present invention, before administration.

Fig. 2 shows the device according to Fig. 1 during the administration with a first shorter penetration depth of the needle.

Fig. 3 shows the device according to Fig. 1 with a second longer penetration depth of the needle.

Fig. 4 shows a cross-section of the device according to Fig. 3 in the direction A-A.

Fig. 5 shows a side view of a needle covering device according to the present invention in a natural size.

Fig. 1 shows a front end of an injection apparatus 10 having a needle 11 attached to its foremost end with a needle attachment device of a conventional design, providing that the needle is in liquid communication with the subcutaneously injectible drug. The injection apparatus may be a conventional single dose syringe or an injection pen containing multiple doses connected to a dosing device. The injection apparatus as such is not a part of the present invention and a wide variety of such devices are understood to be possible to use with the

present invention if they are provided with suitable attachment means to an adjustable needle covering apparatus according to the invention. In the arrangement of Fig. 1, the injection apparatus is attached to an outer stationary tubular sleeve with a releasable attachment device (not shown) which preferably is snap-lock device of a conventional type. Other types of attachment devices are well-known to the skilled person and will not be discussed in further detail. The outer tubular sleeve 40 is connected to a first axially displaceable sleeve 30 which in Fig. 1 is in its foremost position, resting on a shoulder part 43 of stationary sleeve 40 with a flange 33. In this position, the first tubular sleeve 30 covers the needle entirely. Furthermore, the needle covering device comprises an inner adjustable stopping sleeve 20 having a slotted front part through which the needle and its attachment device extends, said front part also is provided with protruding stopping means 24 which co-operates with stopping flange 31 on the inside of sleeve 30 when limiting the penetration depth of needle during injection. Between a flange part 32 inside the axially displaceable sleeve 30 and a shoulder part 22 of the stopping sleeve 20 a helical spring device 50 is extended which surrounds the front part of the injection apparatus. The spring device has a spring force which must be overcome by the user when pressing the needle covering device against the injection site in order to obtain a subcutaneous penetration of the needle. It is preferable to design the needle covering device so a major part of the helical spring device (50) is in a position rear to the point (13) where the needle protrudes from the attachment device (12) in the moment of injection. Such a design will lead to that a major part of the needle is used for the injection and a more comfortable administration for the patient is achieved. At the rear end of the stopping device, diametrically opposite protrusions 21, 21' extend through correspondent slits in the outer stationary sleeve. These features will be explained in more detail below.

To administering a dose from the injection apparatus the needle covering device is pressed gently against the injection site and when overcoming the spring force of the spring device 50, the stopping device 24 and the stopping flange 31 will meet, while needle is forced out through the aperture 34 of the sleeve 30 for a predetermined distance identical to the set distance between said devices 24 and 31 in resting position, see Fig. 2. After actuating the injection apparatus in a conventional manner to expel and administer a given drug quantity, the spring force can return the needle cover device to the position shown in Fig. 1.

A new penetration depth is set by axially displacing the stopping sleeve between its predetermined positions while it performs a sliding helical motion around the front part of the injection apparatus so a new distance between the foremost part of the stopping sleeve and the stopping flange 31 arranged on the inside of the axially displaceable first sleeve 30. The foremost part of the stopping sleeve is preferably an annular stopping flange 24 which hits the preferably annular stopping flange 31 in the stopping position. As best seen in Fig. 5, the setting of a new penetration depth is performed by moving diametrically opposite protrusions 21, 21' of the stopping sleeve simultaneously in the slits 41, 42 and the diametrically opposite slits 41',42', not shown in Fig. 5, of the outer stationary sleeve 40, wherein said protrusions are slidingly fitted, see also Fig. 4 which is a cross-sectional view through the slits. When selecting the longer penetration depth of the needle, as demonstrated in Fig. 3, the protrusions 21, 21' is slidingly moved from the slit 42, 42' to 41, 41' while the stopping sleeve performs helical motion around the injection apparatus. It is to be understood that more slits than demonstrated in Fig. 5 can be used, in order to obtain more than two predetermined penetration depths of the needle. The arrangement with diametrically opposite slits and protrusions shall be regarded as a preferred embodiment of the present invention. The form and number of protrusion and slits may be varied within the scope of the invention to obtain a desired penetration depths that will fit a certain therapeutical application.

Also other ways of axially displacing a stopping sleeve between predetermined positions to set out the axial distance between its foremost part and an axially displaceable spring loaded needle covering first sleeve to obtain corresponding pre-set penetration depths into the subcutaneous fat layer of an injection needle of an injection apparatus connected to said sleeves than by means of said protrusions and slits are conceivable and also part of the present invention as defined by the appended claims.

In many applications it is advantageous to provide the injection apparatus with our without the needle attached thereto to the user in the form of a ready-to-use kit together with the needle cover device. The patient can readily attach the needle cover device to the injection apparatus eventually after removing a temporary needle protecting device and adjust the needle cover to a certain desired injection depth that corresponds to a subcutaneous injection site. It is preferred that the patient selects suitable penetration depths corresponding to subcutaneous injection sites after discussion with a physician, since the depth of the subcutaneous fat layer varies between different individuals.

The adjustable needle cover device of the present invention shall not be regarded as limited for subcutaneous administration, since it can be made equally useful for other forms of adminstration by injection.

Claims

1. A needle covering device for adjusting the penetration depth of a needle connected to injection apparatus, comprising an axially displaceable first tubular sleeve (30) arranged around the front part of said

injection apparatus which at its foremost part surrounds the needle (11) over its entire length, and while overcoming a spring force, is axially displaceable rearwards to expose a predetermined length of the needle **characterized in that** said device further comprises a stationary outer tubular sleeve (40) releasably attached to the injection apparatus and fitted around the front part of said injection apparatus and an inner adjustable tubular stopping sleeve (20) which is axially displaceable between at least two predetermined positions while performing a sliding, helical motion around said front part of said injection apparatus when setting the distance between the foremost part of said stopping sleeve and a stopping flange (31) arranged on the inside of the axially displaceable first sleeve.

2. A device according to claim 1, wherein said spring force is effected by a helical spring device (50) arranged inside the first sleeve (30) surrounding the needle.

3. A device according to claim 2, wherein said helical spring extends between a shoulder part (22) of the stopping sleeve (20) and an inwardly directed flange (32) of first sleeve (30).

4. A device according to claim 2 or 3 **characterized in that** a major part of the helical spring device (50) is in a position rear to the point (13) where the needle protrudes from the attachment device (12) in the moment of injection.

5. A device according to any previous claim **characterized in that** the stationary outer sleeve (40) has at least two radially extended stepwise arranged slits (41, 42), wherein one or several protrusions (21) of the stopping sleeve (20) are slidingly fitted.

6. A device according to claim 5 **characterized in that** the slits (41, 42) are diametrically opposed to correspondent slits on the outer sleeve and corresponding protrusion (21') is arranged on the stopping sleeve.

7. A device according to any previous claim **characterized in that** the outer sleeve (40) is releasingly attached to the injection apparatus with a snap lock device.

8. A method of adjusting the penetration depth of the needle of an injection apparatus in which the needle is covered by a tubular sleeve (30) connected both to stopping sleeve (20) and an outer stationary sleeve (40) **characterized by** axially moving said stopping sleeve (20), which is connected to said stationary sleeve (40), between at least two predetermined positions while it performs a sliding helical motion around a front part of said injection apparatus and thereby setting the distance between the foremost part of said stopping sleeve and a stopping flange (31) arranged inside the sleeve (30) which distance corresponds to the selected penetration depth.

9. A method according to claim 8, wherein the stopping sleeve is connected to the stationary sleeve by at least one protrusion (21) slidingly fitted in radially stepwise arranged slits.

10. A method of administering a drug by subcutaneous injection while obtaining a correct injection depth in the subcutaneous fat layer **characterized by** the measures of:

- attaching a sleeve formed needle covering device to the front end of an injection apparatus;
- estimating the depth of the subcutaneous fat layer at the injection site;
- setting a penetration depth less than the value of the depth of the subcutaneous fat layer by adjusting the needle covering device in a predetermined manner; and
- while overcoming a spring force pressing the needle out of said covering device and into the subcutaneous fat layer and administering the drug.

11. A method according to claim 10, wherein the needle covering device comprises, in connection, an outer stationary sleeve (40), an axially displaceable needle covering sleeve (30) and a stopping sleeve and said needle covering device is adjustable by axially moving said stopping sleeve between at least two predetermined positions and thereby setting the distance between the foremost part of said stopping sleeve and said needle covering sleeve which distance corresponds to the selected penetration depth.

12. A method according to claim 11 **characterized by** performing a sliding helical motion around the front part of the injection device when setting a selected penetration depth with the stopping sleeve.

13. A method according to claim 12 **characterized by** setting the selected penetration depth by means by slidingly moving protrusions (21, 21') of the stopping sleeve in the stepwise arranged slits (41, 42) of the outer sleeve.

14. A kit for subcutaneous injection comprising:

a) an injection apparatus containing one or several doses of a subcutaneously injectible preparation which is provided with attachments

means for tubular sleeve formed needle covering device

b) a tubular needle covering device releasingly attachable to the injection device provided with means for adjusting the penetration depth of the needle into the subcutaneous fat layer, said device comprises a spring which has a spring force that must be overcome when pressing the needle into the injection site.

15. A kit according to claim 14, wherein the needle covering device comprises, in connection, an outer stationary sleeve (40), an axially displaceable needle covering sleeve (30) and a stopping sleeve (20) and said needle covering device is adjustable by axially moving said stopping sleeve between at least two predetermined positions and thereby setting the distance between a foremost part of said stopping sleeve and said needle covering sleeve which distance corresponds to the selected penetration depth.

16. A kit according to claim 15, wherein the stopping sleeve performs a sliding helical motion around the front part of the injection device when setting a selected penetration depth with the stopping sleeve.

17. A kit according to claim 16, wherein the selected penetration depth is set by means of slidingly moving protrusions (21, 21') of the stopping sleeve in the stepwise arranged slits (41, 42) of the outer sleeve.

18. A kit according to claim 14 comprising the tubular needle covering device according to any of claims 1 to 7.

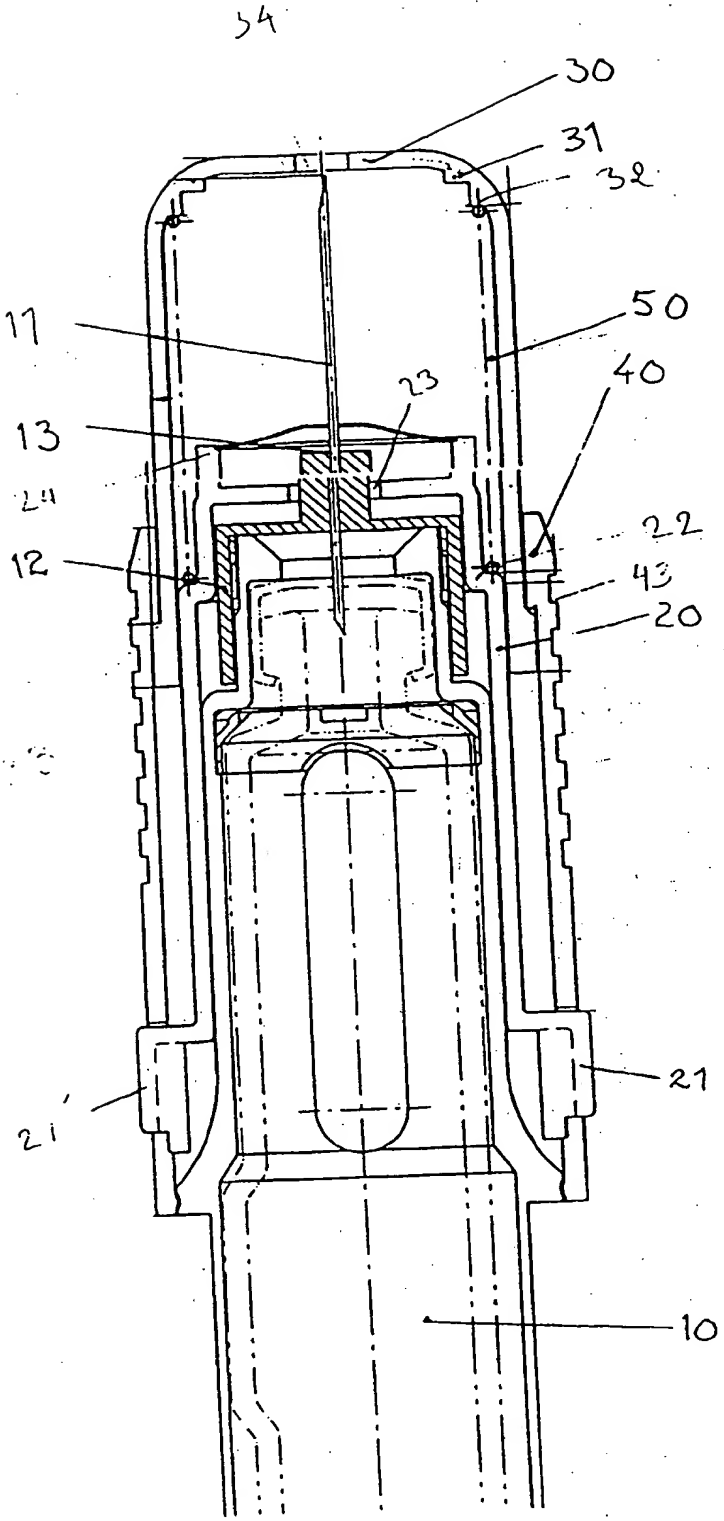

Fig. 1

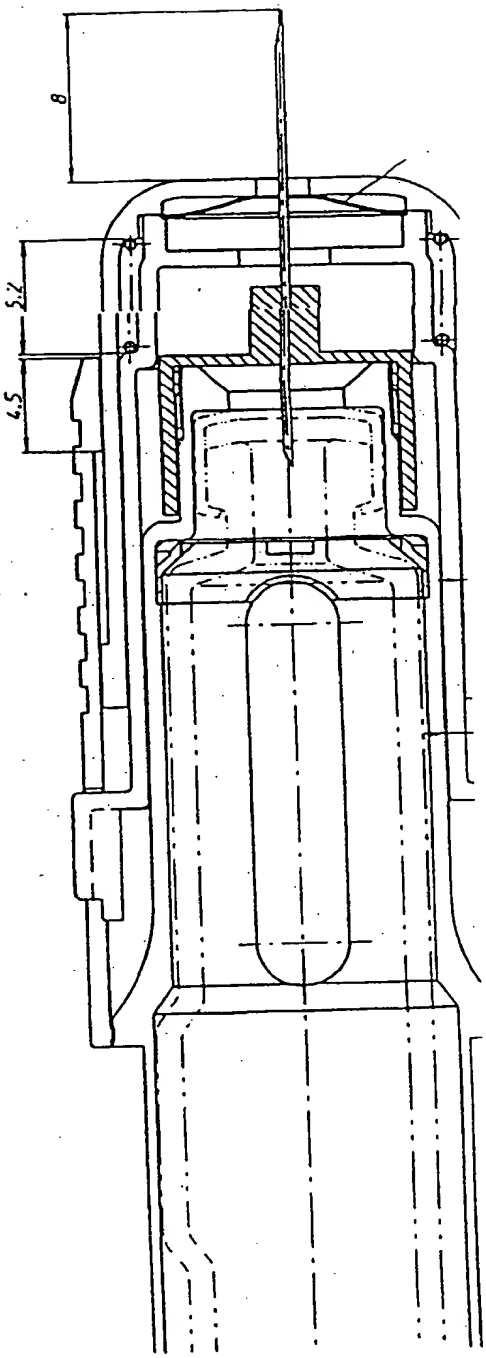

Fig. 2

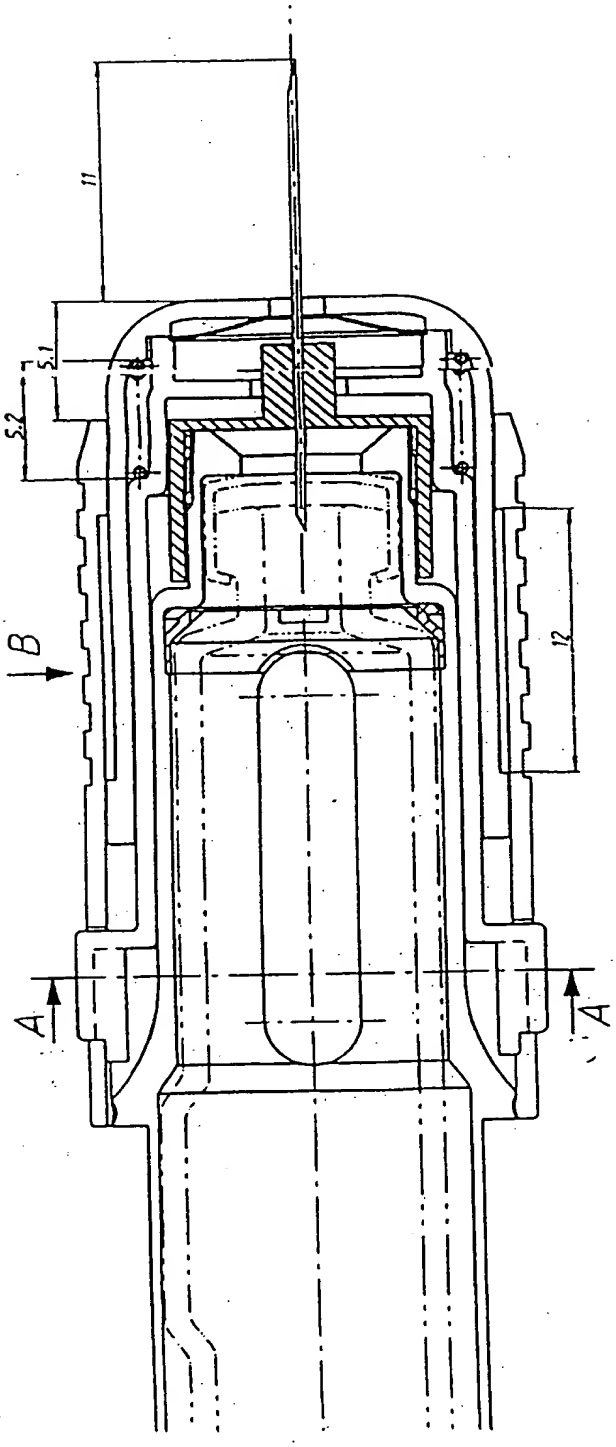

Fig. 3

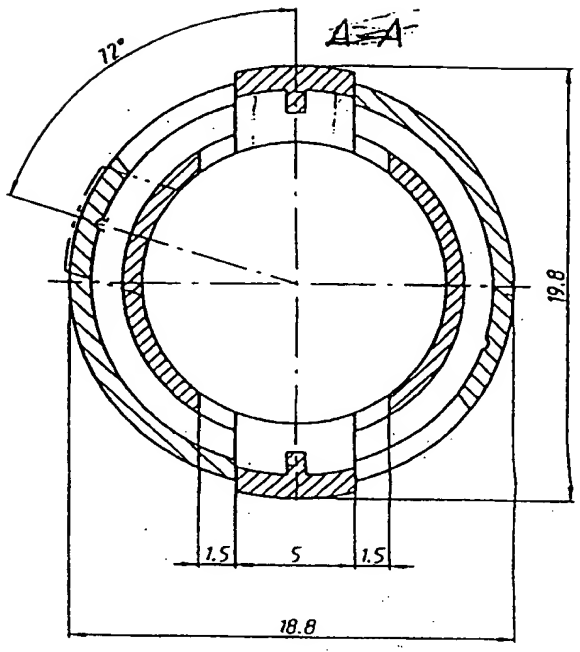

Fig. 4

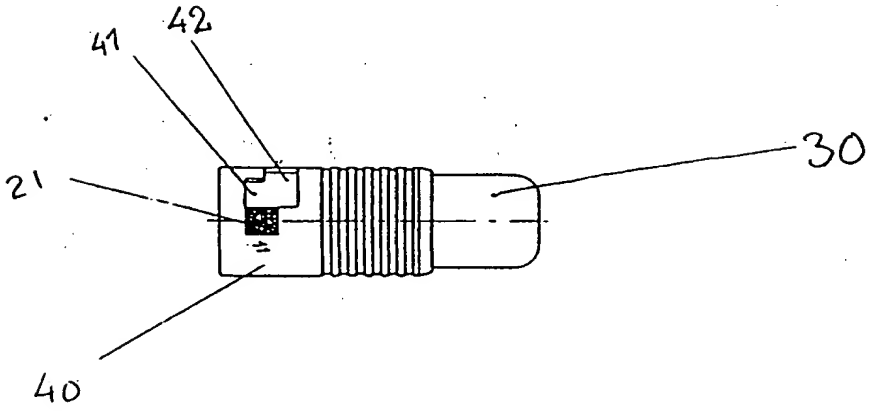

Fig. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 85 0116.3

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	US, A, 5141496 (TINO DALTO ET AL), 25 August 1992 (25.08.92) * figure 1, abstract *	10,14	A61M 5/20 A61M 5/46
A		1-18	

TECHNICAL FIELDS SEARCHED (Int. Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	10 September 1996	MAY HALLNE

CATEGORY OF CITED DOCUMENTS

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